DRUG INFORMATION ASSOCIATION

42nd Annual Meeting

eCTD: Module 1

from submission to reviewer

Bronwyn Collier, B.S.N.
Associate Director for Regulatory Affairs
Center for Drug Evaluation and Research
FDA

Philadelphia 2006

PIONEERS IN CONSUMER PROTECTION
1906 - 2006
FDA Centennial
LEADERS IN THE SCIENCE OF PUBLIC HEALTH

Topics

- How information in Module 1 is used for
  - Processing
  - Assignment for review
  - Application management
- eCTD TOC mapping to regulations/legislation
- Application of eCTD TOC headings/subheadings to Module 1 documents

Module 1: Regional Documents

- Application status
- Sponsor information
- Entry to special regulatory programs
- Satisfies some regulatory requirements
- Guides response
- Document processing
- Facilitate review assignment

From receipt to reviewer…

- Where to send your submission
- Providing identifying information for processing

Document Processing

- Receive submission
  - Date stamp
  - Check for readability, application form, cover letter
- Data entry into tracking systems
- Review by RPM
- Data entry if corrections/additions needed
- Load into Electronic Document Room (EDR)
- Assignment to review team and any consultants

Application/Submission Identity

Module 1 is the only place where application administrative/identification information is provided in "machine readable" form

Where to send your eCTD

CDER Central Document Room
Food and Drug Administration
Center for Drug Evaluation and Research
5901-B Ammendale Road
Beltsville, Maryland 20705-1266

FDA Electronic Submissions Gateway (ESG)

Office of Generic Drugs Document Room
HFD-600
Metro Park North II
7500 Standish Place
Rockville, MD 20855

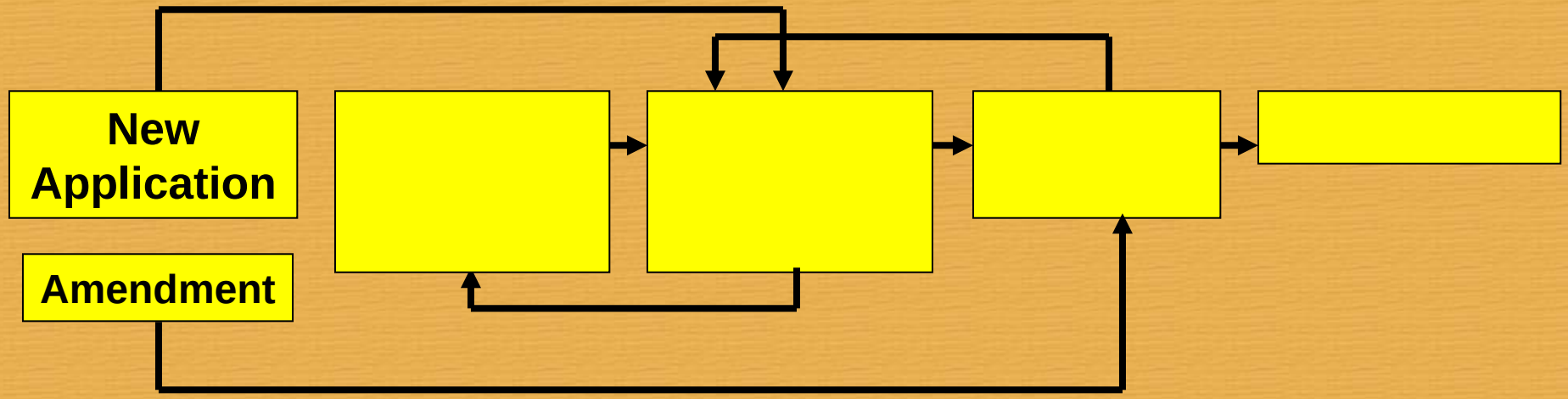
CBER Document Room
HFM-99, Suite 200N
1401 Rockville Pike
Rockville, MD 20862-1448

US Mail & Courier Delivery

- Address to Central Document Room

US Mail & Courier Delivery

- Resist the urge to send archive documents directly to the project manager or White Oak document room!



Forms and Cover Letters

Forms and cover letters should be considered "new" documents submitted to an application

Forms and Cover Letters

- Forms
  - Fill out completely
  - http://www.fda.gov/opacom/morechoices/fdaforms/default.html
- Cover Letters
  - Identification of application number
  - Bold identification of submission content
  - Brief description of submission content
  - Any request for input on specific questions or issues
  - Implementation date (e.g., new protocols, protocol changes, manufacturing changes)

Cover letter: content identification

05 May 2006

John M. Doe, MD, Acting Director
Division of XYZ Products
Office of Drug Evaluation IX
Center for Drug Evaluation and Research
Food and Drug Administration
5901-B Ammendale Road
Beltsville, Maryland 20750-1266

RE: New Drug Application 000000
A000X: Response to Letter from FDA dated 07 December 2004
Product: Best One (feelbetteron) Tablets
Indication: Treatment for hangnail
Sponsor: A-One Pharmaceuticals

Dear Dr. Doe:

Cover letter: content identification

05 May 2006

John M. Doe, MD, Acting Director
Division of XYZ Products
Office of Drug Evaluation IX
Center for Drug Evaluation and Research
Food and Drug Administration
5901-B Ammendale Road
Beltsville, Maryland 20750-1266

RE: New Drug Application 000000
A000X: **Information Amendment: Clinical Information**
Response to Letter from FDA dated 07 December 2004
Product: Best One (feelbetteron) Tablets
Indication: Treatment for hangnail
Sponsor: A-One Pharmaceuticals

Dear Dr. Doe:

Submission & Receipt Dates

- Submission date
  - Date on the form or cover letter, whichever is the latest
- Receipt date
  - Physical media- date received in Document Room
  - Gateway
    - Official receipt time 8:00-4:30 EST
    - Submissions received outside of official hours- next business day

TOC Mapping

CFR Citation		eCTD/STF Heading		
NUMBER	TITLE	MODULE	NUMBER	TITLE
312.7(d)	Charging for and commercialization of investigational drugs	1	1.12.2	Request to Charge
312.10	Waivers	1	1.12.5	Request for a waiver
312.23 (a)(1)	Cover sheet (Form FDA 1571)	1	1.1.1	Application form: FDA form 1571
312.23(a)(2)	Table of Contents	N/A	N/A	N/A
314.50(h)	Patent Information	1	1.3.5.1	Patent Information

Module 1 Headings and Subheadings: *What's between the lines…*

Forms

- 1.1 Forms– not all forms are included in this section
  - 3542 and 3542A (Patent certifications)
  - 1572 (Investigator information)

Requests & Supporting Documents

- 1.6.2 Meeting background materials
  - A protocol may belong in Module 4 or 5
- 1.8 Special Protocol Assessment request
  - Request- Module 1
  - Protocol- Module 3, 4, or 5
- 1.10 Dispute Resolution
  - Request- Module 1
  - Supporting information may be in other modules

Miscellaneous Information & Annual Reports

- 1.11 Information amendment- *use <u>only</u> for information that doesn't fit into Modules 2-5*
- 1.13 Annual report
  - Most parts will fit in Module 1
  - A study report or a protocol amendment may belong in Module 4 or 5

Labeling

- Targeted Product Profile (TPP)
  - 1.14.4.1 Investigator's Brochure
- SPL
  - Must be placed in the SPL folder
  - Link to the appropriate subheading in the TOC
    - 1.14.1.3 Draft labeling text
    - 1.14.2.3 Final labeling text

What if there's no available heading?

- Special Programs
  - Accelerated Approval
  - Priority Review cover
  - Subpart E
- General Investigational Plan (outside of an Annual Report)

Make use of the Cover Letter

Contact Information

- Gateway
  - esgprep@fda.gov
- eCTD
  - esub@cder.fda.gov
- Regulatory questions
  - Bronwyn.collier@fda.hhs.gov